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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,782	10/12/2001	William M. Grosse	21402-157 (Cura-457)	2201

30623 7590 06/16/2004

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,782	GROSSE ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, and 41, as specifically drawn to an isolated polypeptide comprising an amino acid sequence selected from the group consisting of: SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, and 26, classified in class 530, subclass 350.
(Upon election of Group I, the applicant must choose ONE polypeptide SEQ ID NO from those listed in Claim 1 and its corresponding nucleic acid SEQ ID NO from Claim 3, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

II. Claims 5-14, 39, and 42, as specifically drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide, classified in class 536, subclass 23.1.
(Upon election of Group II, the applicant must further choose ONE nucleic acid SEQ ID NO from those listed in Claim 8 and the polypeptide SEQ ID NO it encodes from those listed in Claim 5, as each SEQ ID NO is a distinct invention, NOT a species)

III. Claims 15-17, 40, and 43, as specifically drawn to an antibody that binds immunospecifically to a polypeptide, classified in class 530, subclass 388.1.
(Upon election of Group III, the applicant must further choose ONE polypeptide SEQ ID NO which the antibody of claim 15 immunospecifically binds from those listed in Claim 1, as each SEQ ID NO is a distinct invention, NOT a species)

IV. Claim 18, as specifically drawn to a method of determining the presence or amount of a polypeptide in a sample, classified in class 435, subclass 7.1.

V. Claims 19-21, as specifically drawn to a method of determining the presence or amount of a nucleic acid molecule in a sample, classified in class 435, subclass 6.

VI. Claims 22-24, as specifically drawn to a method of identifying an agent that binds to a polypeptide or modulates the expression or activity of a polypeptide, classified in class 435, subclass 4.

VII. Claim 25, as specifically drawn to a method of modulating the activity of a polypeptide, classified in class 514, subclass 2.
(Upon election of Group VII, the applicant must choose ONE polypeptide SEQ ID NO from those listed in Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

VIII. Claims 26-27, 29, and 48, as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering a polypeptide, wherein said disorder is cardiomyopathy and atherosclerosis, classified in class 424, subclass 184.1.
(Upon election of Group VIII, the applicant must choose ONE polypeptide SEQ ID NO from those listed in Claim 48, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

IX. Claims 26, 28-29, and 48, as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering a polypeptide, wherein said disorder is related to cell signal processing and metabolic pathway modulation, classified in class 424, subclass 184.1.
(Upon election of Group IX, the applicant must choose ONE polypeptide SEQ ID NO from those listed in Claim 48, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

X. Claims 30-31, and 33, as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering a nucleic acid, wherein said disorder is cardiomyopathy and atherosclerosis, classified in class 514, subclass 44.
(Upon election of Group X, the applicant must further choose ONE nucleic acid SEQ ID NO from those listed in Claim 8, as each SEQ ID NO is a distinct invention, NOT a species)

XI. Claims 30, and 32-33, as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering a nucleic acid, wherein said disorder is related to cell signal processing and metabolic pathway modulation, classified in class 514, subclass 44.
(Upon election of Group XI, the applicant must further choose ONE nucleic acid SEQ ID NO from those listed in Claim 8, as each SEQ ID NO is a distinct invention, NOT a species)

XII. Claims 34-35, 37, and 49 as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering an antibody, wherein said disorder is diabetes, classified in class 424, subclass 130.1.
(Upon election of Group XII, the applicant must further choose ONE polypeptide SEQ ID NO which the antibody of claim 15 immunospecifically binds from those listed in Claim 1, as each SEQ ID NO is a distinct invention, NOT a species)

XIII. Claims 34, and 36-37, as specifically drawn to a method of treating or preventing a NOVX-associated disorder by administering an antibody, wherein said disorder is related to cell signal processing and metabolic pathway modulation, classified in class 424, subclass 130.1.
(Upon election of Group XIII, the applicant must further choose ONE polypeptide SEQ ID NO which the antibody of claim 15 immunospecifically

binds from those listed in Claim 1, as each SEQ ID NO is a distinct invention, NOT a species)

XIV. Claims 44-45, as specifically drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of a polypeptide, classified in class 424, subclass 9.1.
(Upon election of Group XIV, the applicant must choose ONE polypeptide SEQ ID NO from those listed in Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

XV. Claims 46-47, as specifically drawn to a method of determining the presence of or predisposition to a disease associated with altered levels of a nucleic acid, classified in class 424, subclass 9.1.
(Upon election of Group XV, the applicant must further choose ONE nucleic acid SEQ ID NO from those listed in Claim 8, as each SEQ ID NO is a distinct invention, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III, represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group II is drawn specifically to a polynucleotide that encodes a polypeptide, whereas Group III is drawn specifically to an antibody.

The invention of Groups IV-XV are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group IV is drawn to a method of determining the presence or amount of a polypeptide, whereas Group X is drawn to a method of treatment by administering a nucleic acid.

The invention of Group I and the methods of Groups VI, XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in a materially different method such as being used to identify an agent that binds to the polypeptide or administered to a mammal for the treatment of a pathological state.

The invention of Group II and the methods of Groups V, X are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group II can be used in a materially different method such as being used to access the amount of an antibody in a sample or the nucleotide can be administered to a mammal for the treatment or prevention of a NOVX-associated disorder.

The invention of Group III and the methods of Groups XII, VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in a materially different method such as preventing diabetes or the antibody can be administered to a mammal for the treatment of a pathological state.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER